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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/716,853 | 11/20/2003 | Eric John Gandras | | 7096 |

7590
Eric J. Gandras, M.D.
29 Vanderbilt Drive
Great Neck, NY 11020

04/19/2007

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| EXAMINER |
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GRAY, PHILLIP A

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| ART UNIT | PAPER NUMBER |
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3767

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/19/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/716,853

Applicant(s)

GANDRAS, ERIC JOHN

Examiner

Phillip Gray

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31, 33-44, 46-57 and 59-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31, 33-44, 46-57, and 59-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to applicant's communication of 1/19/2007. Currently amended claims 1-31, 33-44, 46-57, and 59-64 are pending and stand rejected. Claims 32, 45, and 58 were cancelled previously by applicant.

Response to Arguments

Applicant's arguments filed 1/19/2007 have been fully considered but they are not persuasive. Applicant has added claim language of "wherein the second tapered section has at least one curve". This claim limitation was previously incorporated in cancelled claims and further was rejected as disclosed in the prior art of record, namely (Engelson). It is examiners position, as described in rejection below, that Engelson does disclose a primary and secondary curved sections with primary and secondary tapered sections. Applicant is reminded that during examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). Given a broad reading the claims as currently written fail to distinguish themselves over the prior art of record.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "a CURVE within his end/distal tip section") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In summation the elements disclosed in Engelson are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10, 12-20, 23, 25-26, 28-30, 33-35, 38-42, 44, 46-48, 51-55, 57, 59-61, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Engelson et al. (U.S. Patent Number 6,030,369).

Engelson discloses a micro catheter shaft. Engelson discloses a catheter for use in angiographic procedures. The Engelson soft flexible elastic catheter (as in figure 1) has a primary curve (between element 106 and 104) and secondary curve (between 104 and 102), a first tapered section and second tapered section (see figures 2,3,4, and 5) with a flexible soft elastic tapered end section (120, 112). Engelson further teaches that the second tapered section tapers from an inner diameter of 0.035 inches, and wherein the outer diameter tapers from 4 to 3 French with an overall length of between 76cm and 87cm (see paragraph at column 4 line 6) or variable.

Concerning claims 2, and 17, 18, 19; it is taught in Engelson that the catheter may be formed from a group of plastics that includes polyurethane, polyethylene and polyether block amide copolymer (see paragraphs at column 4 line 51) and that a coating could be hydrophilic (column 2 line 31) further a hydrophilic coating is a well known catheter coating in the art and it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Concerning claim 10 and 12, Engelson discloses and teaches that the angle of the primary curve is within a range between 180 and 420 degrees (shown in figure 1) and the secondary curve is between 90 and 100 degrees (fig 1).

Concerning claim 13,14, 44, and 57; Engelson teaches that the catheter could be formed from a braided stainless steel material (see paragraph at column 1 line 26). As Engelson teaches, it is well known in the art that the braided material be stainless steel, but if not implicitly known it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Concerning claims 15 and 16, Engelson would include a catheter impregnated with a tungsten radioopaque material (See column 4 line 44).

Concerning claims 20 and 23, the Engelson catheter has a polyurethane hub at its origin (see element hub near 112 and 110)

Concerning claim 25 and 26, Engelson discloses a polyurethane straightner (near element 106), which could be between 2 and 3 cm. Applicant is advised that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It would appear that the elements of 110 and 106 would straighten the catheter. There is no other functional, operational, or spatial claim language that would not be anticipated by the elements of 110 and 106, as claims are currently written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9, 11, 21-22, 24, 27, 31, 36, 37, 43, 49, 50, 56, 62, 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelson et al.

Concerning claims 5, 6, 7, 8, 9; Engelson discloses the claimed invention except for disclosing the exact size specifications of certain centimeter lengths of the catheter between the curves and tip. It would have been obvious to one having ordinary skill in the art at the time the invention was made to size the catheter with the exact dimensions of length of tapered catheter curve sections, since such a modification

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would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Concerning claim 11; Engelson discloses the claimed invention except for the primary curve is 360 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the 180 degree curve to 360 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955).

Concerning claims 21-22, 24; Engelson discloses the claimed invention except for the specific hub length and dimensions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create a hub with the specific dimensions as in the claim limitations, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Concerning claim 27, 36, 37, 49, 50, 62, and 63; Engelson discloses the claimed invention except for the straightner, tapered end section, and second tapered section being formed separately removable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the straightner, tapered end section, and second tapered section separately removable, since it has been held that

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constructing a formerly integral structure in various elements involves only routine skill in the art. *Newin v. Erlichman*, 168 USPQ 177 (BdPatApp&Int 1969).

Concerning 31, 43, and 56; Engelson discloses the claimed invention except for making the catheter out of a germ retarding material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the catheter formed from a germ retarding material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


PAG

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

